

VACCINE ADVISORY

From the Texas Department of State Health Services Immunization Branch

The goal of the Vaccine Advisory is to disseminate, in a timely manner, practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch. The Immunization Branch welcomes readers' input to improve the contents of this document.

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April 7, 2009

Advisory No. 11. New Rotavirus Vaccine Administration Guidelines

In April 2008 a new rotavirus vaccine produced by GlaxoSmithKline, Rotarix[®], was licensed for use among U.S. infants. In June 2008, the Advisory Committee on Immunization Practices (ACIP) updated its recommendations to include the use of Rotarix[®]. The new recommendations which update and replace the 2006 ACIP statement for prevention of rotavirus gastroenteritis are published in the February 6 issue of *Morbidity and Mortality Weekly Report* and can be viewed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm>.

This advisory provides a summary of the new recommendations.

This advisory contains:

1. Background information
2. Summary of ACIP's recommendations for the use of rotavirus vaccine
3. Texas Vaccines for Children program
4. ImmTrac
5. Texas school and child-care facilities requirements for rotavirus vaccine
6. Epidemiology and surveillance
7. Reporting vaccine adverse events
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1) Background

Rotavirus is a viral infection and leading cause of severe diarrhea in infants and young children. Almost all children will experience rotavirus infection; while some children experience mild symptoms of rotavirus, infection can be severe and lead to dehydration that can be fatal. In the

United States, children are at the greatest risk for severe rotavirus disease from 3 to 24 months of age.

The U.S. Food and Drug Administration (FDA) has approved 2 oral vaccines for the prevention of rotavirus gastroenteritis: RotaTeq[®] (RV5) and Rotarix[®] (RV1).

2) Summary of ACIP Recommendations

The ACIP recommendations for the prevention of rotavirus gastroenteritis among infants and children are summarized below:

Changes to recommendations from the 2006 ACIP statement are as follows:

- ACIP provides recommendations for use of a second rotavirus vaccine, Rotarix[®], to be administered in a 2-dose series at ages 2 and 4 months.
- The maximum age for dose 1 of rotavirus vaccine is 14 weeks and 6 days of age (previously, the recommendation was 12 weeks).
- The maximum age for the last dose of rotavirus vaccine is 8 months and 0 days (previously, the recommendation was 32 weeks).
- The minimum interval between doses of rotavirus vaccine is 4 weeks; no maximum interval is set (previously, the recommendation was 4-10 weeks interval between doses).
- The updated guidelines describe considerations that support rotavirus vaccination of HIV-exposed or infected infants.
- Rotavirus vaccine may be administered at any time before, concurrent with, or after administration of any blood product, including antibody-containing products, following the routinely recommended schedule for rotavirus vaccine (previously, the recommendation was to defer vaccination for 42 days after receipt of an antibody containing product, if possible).

Recommendations for routine administration of rotavirus vaccine

- For routine vaccination of U.S. infants, two different rotavirus vaccine products are licensed: RotaTeq[®] (RV5), manufactured by Merck & Co, and Rotarix[®] (RV1), manufactured by GlaxoSmithKline. The products differ in composition and schedule of administration. ACIP does not express a preference for either RV5 or RV1.
- RotaTeq[®] is to be administered orally in a 3-dose series with doses given at ages 2, 4, and 6 months.
- Rotarix[®] is to be administered orally in a 2-dose series with doses given at ages 2 and 4 months.

The first dose of rotavirus vaccine should be administered from age 6 weeks through age 14 weeks 6 days. Vaccination should not be initiated for infants of age 15 weeks 0 days or older.

Simultaneous Administration

Rotavirus vaccine can be administered together with DTaP vaccine, Hib vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, and pneumococcal conjugate vaccine.

Interchangeability of Rotavirus Vaccines

- ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. However, vaccination should not be deferred if the product used for previous doses is not available or is unknown. In this situation, the provider should continue or complete the series with the product available.
- If any dose in the series was RotaTeq[®] or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given. All doses should be administered by age 8 months and 0 days.

Contraindications

Rotavirus vaccine should not be administered to infants who have a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of rotavirus vaccine or to a vaccine component. Latex rubber is contained in the Rotarix[®] oral applicator, so infants with a severe (anaphylactic) allergy to latex should not receive Rotarix[®]. The RotaTeq[®] dosing tube is latex-free.

3) Texas Vaccines for Children program

The Texas Vaccines for Children program offers the RotaTeq[®] vaccine for use by enrolled providers. This vaccine is listed on the Biological Order Form and can be obtained using normal ordering procedures.

For more information, please contact your health service region or TVFC consultant.

4) ImmTrac

ImmTrac users can report Rotarix[®] vaccine administered using the ImmTrac code "**ROTAV-Mono**" and RotaTeq[®] vaccine using the ImmTrac code "**ROTAV-Pent**".

Although ImmTrac can record the administration of rotavirus vaccine, the ImmTrac immunization scheduler will not generate recommendations for either vaccine at this time. The provider should review the child's immunization history and consult ACIP recommendations to determine if administration of rotavirus vaccine is appropriate.

For more information about ImmTrac, please visit www.ImmTrac.com.

5) Texas school and child-care facilities requirements for rotavirus vaccine

Currently, rotavirus vaccine is not required for school or child-care attendance.

6) Epidemiology and surveillance

Rotavirus is a virus that causes severe diarrhea, often accompanied by vomiting, fever, and dehydration, mostly in babies and young children. Rotavirus is mainly transmitted from person to person via the fecal-oral route. It is the leading cause of diarrhea in infants and young children, accounting for an estimated 527,000 deaths annually worldwide among

children less than 5 years of age. Adults can also be infected, though the disease tends to be mild. The incubation period for rotavirus disease is approximately 2 days.

Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Before rotavirus vaccine was licensed for use, rotavirus was responsible for more than 400,000 doctor visits, more than 200,000 emergency room visits, 55,000 to 70,000 hospitalizations, and 20–60 deaths in the United States each year. In winter months, approximately 50% of hospitalizations and emergency department visits and 30% of outpatient visits for acute gastroenteritis among U.S. children aged <3 years are caused by rotavirus.

Children are most likely to get rotavirus diarrhea between November and May, depending on the part of the country they live in.

Rotavirus is not a reportable condition in Texas.

7) Reporting adverse vaccine events

Clinically significant adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Adverse events from privately purchased vaccine may be reported directly to VAERS at <http://vaers.hhs.gov/>. Secure web-based reporting is available on the VAERS website. Contact 800-VAC-RXNS for forms and information.

In Texas, reports of events following vaccination at public health clinics or with vaccine provided through public funding such as the Texas Vaccines for Children (TVFC) program should be reported through the Texas Department of State Health Services, Immunization Branch (MC 1946), P.O. Box 149347, Austin, TX 78714-9347. The pre-addressed and postage-paid VAERS form with this address can be obtained by calling the Immunization Branch. A copy of the form is also available in the TVFC toolkit. To request a VAERS form or additional information, call the VAERS contact in your area:

- **In Texas:** (800) 252-9152
- **For Bexar County:** (210) 207-2087
- **For City of Houston:** (713) 558-3518

8) Resources (Vaccines)

- The *American Academy of Family Physicians (AAFP) News Now* article: Check Out New Rotavirus Vaccine Guidance:
<http://www.aafp.org/online/en/home/publications/news/news-now/clinical-care-research/20080715rotavirus-recs.printerview.html>
- Rotavirus Vaccine Information Statement:
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-rotavirus.pdf>
- Rotarix[®] prescribing information:
<http://www.fda.gov/cber/label/rotarixLB.pdf>

9) Resources (Disease)

- *Morbidity and Mortality Weekly Report: Rotavirus Activity:*
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm57e625a1.htm>
- Medline Plus: Rotavirus Infections:
<http://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v%3Aproject=medlineplus&query=rotavirus+disease>

We hope you generously forward this advisory to others who may benefit from this information.

Texas Department of State Health Services Immunization Branch (MC 1946)
P.O. Box 149347, Austin, Texas, 78714-9347. (512) 458-7284 or (800) 252-9152
www.ImmunizeTexas.com

